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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SHAW, AMANDA MARIE	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 11/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/765,943	NUMAJIRI, YASUYUKI	
	Examiner	Art Unit	
	Amanda M. Shaw	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15 and 17-26* is/are pending in the application.

4a) Of the above claim(s) *1-5,10-14 and 20-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-9, 15-19, and 25-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. On October 20, 2006 a final office action was mailed. On October 30, 2006 the applicant's attorney contacted the examiner because the examiner inadvertently did not apply an art rejection to newly added claim 26. The applicant's attorney was told that a supplemental office action would be issued. Accordingly the previous office action is vacated and a new office action is set forth below.

This action is in response to the amendment filed September 21, 2006. Applicant's arguments have been fully considered but are not persuasive to overcome all grounds of rejection. All rejections not reiterated herein are hereby withdrawn. This action is made **final.**

Claims 1-15 and 17-26 are currently pending. Claims 1-5, 10-14, and 20-24 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected subject matter, there being no allowable generic or linking claim. The election was made with traverse in the response filed on May 30, 2006

Claims 6, 8-9, and 25 have been amended. Claim 26 is newly presented. Therefore Claims 6-9, 15, 17-19, and 25-26 will be addressed herein.

Information Disclosure Statement

2. The information disclosure statements (IDS) submitted on 3/17/2004 has been considered. It is also noted that the applicants have stated that they provided a statement of relevance for the non-English document on the IDS submitted March 17,

2004. According to the IDS the concise explanation of relevance for the non-English document is found, inter alia, in the specification where it is cited and/or in the attached English language abstract. Since JP 2001-147231 is in Japanese, only the abstract **has been** considered by the examiner.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

THE FOLLOWING IS A NEW GROUND OF REJECTION NECESSITATED BY APPLICANTS AMANEDMENTS TO THE CLAIMS:

Claim 26 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

In the instant case the specification does not appear to provide support for the amendment which recites a method "further comprising a step of identifying the DNA microarray." It is noted that the applicant points to Figures 5A-5C for support. Specifically the specification teaches that Fig 5A represents how upon receiving a test request, the correspondence between the subject (subject information) and the

specimen number is registered in the storage device. Fig 5B represents how during the testing process the correspondence between the registered specimen number and the serial number of the DNA microarray used for the test is registered in the storage device. Fig 5C shows how when the personal identification code is obtained by digitizing a hybridization pattern, corresponding subject information, and test result information are registered in correspondence with each other. The teachings in the specification do not disclose how a microarray is identified. Thus the specification does not provide specific support for identifying the DNA microarray.

Claim Rejections - 35 USC § 112

4. THE FOLLOWING IS A NEW GROUND OF REJECTION NECESSITATED BY APPLICANTS AMANEDMENTS TO THE CLAIMS:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 26 is indefinite over the recitation of the phrase "further comprising a step of identifying the DNA microarray". This phrase in considered indefinite because it is unclear how the DNA microarray is being identified.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 6, 7, 15, 18, and 25 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Beecham (US Patent 5876926 Issued 1999) in view of Staub (US Patent 6187540 Issued 2001) and further in view of Wohlgemuth (US Patent 6905827 Filed 2002) for the reasons set forth in the Office Action of 6/21/2006 and reiterated below.

Regarding Claim 6 Beecham teach a method comprising collecting a sample from a test subject and taking biometric data (i.e. gene sequences) from the test subject. First the biometric data is read to determine the identity of the subject and then the sample can be screened for infectious disease monitoring (e.g. HIV) or for genetic testing (e.g. BRCA1 gene). The biometric data permit a high order of probability of correlation of the test subject with the sample and with test results derived from the sample (Abstract, Columns 4, 5, and 10).

Beecham et al do not teach a method which utilizes a DNA microarray to determine the identity of a subject and to test a sample for a disease or genetic condition.

However Staub teach that DNA microarrays can be used to determine the identity of newborn babies. Specifically Staub et al teach that the arrays can comprise thousands of oligonucleotide probes. Sample nucleic acid is allowed to hybridize with the probes and the hybridization conditions can be varied so that sample nucleic acid will only hybridize to a given probe if a perfect match is found. The hybridization pattern is then read and the identity of the subject can be determined (Column 7).

Additionally Wohlgemuth et al teach that cDNA microarrays can be used to detect the expression level on one or more genes and thereby enable one to diagnose or monitor disease (Abstract). Wohlgemuth also teach that DNA microarrays can have several subsets of probes which can be used for different purposes. Specifically Wohlgemuth et al teach that a diagnostic nucleotide set identified as a subset of sequences on a cDNA microarray can be utilized for diagnostic (or prognostic, or monitoring, etc.) purposes on the same array from which they were identified (column 48).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Beecham et al so as to have analyzed the biometric data using a DNA microarray comprising a set of probes which can be used to determine the identity of a subject and a set of probes which can be used to test the sample for a disease or genetic condition in order to have achieved the benefits of using a method which allows for a powerful means of analyzing genetic information which utilizes automated scoring techniques and sophisticated data analysis software for collecting large amounts of data very quickly. Additionally having both

probe sets on one microarray permits a high order of probability of correlation of the test subject with the sample and the test results derived from the sample.

Regarding Claim 7 Beecham et al teach a method further comprising a storage unit configured to store the identity of the subject and a past test result. Specifically Beecham et al teach a method wherein the biometric indica (i.e. gene sequences) and the test results are stored as a single record in a data base (Column 7).

Regarding Claim 15 Beecham et al teach a method further comprising obtaining identification information of the subject recorded on a medical card held by the subject and comparing the information on the card to the information obtained from the analysis of the first set of probes to determine if the identities match. Specifically Beecham et al teach a method for retrieving medical data from a database. The method includes steps of providing a biometric reading by a user (such as a card), receiving medical data from a database when the biometric reading positively correlates with a biometric reading associated with the medical data stored in the database and displaying the medical data only in response to the user's biometric reading whose medical records are being accessed (Column 8).

Regarding Claim 18 Beecham teach a method wherein a warning is given when it is determined as a result of comparison in the comparison step that the subject identified on the basis of the first DNA probe group does not coincide with that recorded on the medical information card. Specifically Beecham teach that when the biometric data submitted by the user does not match stored biometric data the data retrieval

process is either terminated or the user is asked to enter new or revised biometric data (Column 18). This is being interpreted as a warning.

Regarding Claim 25 Beecham teach a method wherein the reading of the hybridization pattern of the second DNA probe group is inhibited if it is determined as a result of comparison in the comparison step that the subject identified on the basis of the first DNA probe group does not coincide with that recorded on the medical information card. Specifically Beecham teach that when the biometric data submitted by the user does not match stored biometric data no stored medical information can be released until the biometric data being entered by the user matches the biometric data stored in the database (column 18).

6. Claims 8 and 9 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Beecham (US Patent 5876926 Issued 1999) in view of Staub (US Patent 6187540 Issued 2001) and Wohlgemuth (US Patent 6905827 Filed 2002) and in further view of Noblett et al (US Patent 6362004 Issued 2002) for the reasons set forth in the Office Action of 6/21/2006 and reiterated below.

The teachings of Beecham, Staub, and Wohlgemuth are presented above in paragraph 5.

The combined references do not teach that the DNA microarray has a first indicator which indicates the first DNA probe group and a second indicator which indicates the second DNA probe group.

However Noblett et al teach the use of fiducial marks on microarrays to precisely determine the location of each probe on the array. Noblett et al teach that microarrays may contain multiple fiducials which can be used for positioning. Additionally Noblett teaches that fiducials can be used to differentiate between arrays when there are multiple arrays on a microarray (Column 7).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Beecham et al so as to have used a DNA microarray comprising a set of fiducials in order to have achieved the benefits of Noblett of using a method utilizes fiducial marks in order to determine the location of each probe on the array.

7. Claims 17 and 19 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Beecham (US Patent 5876926 Issued 1999) in view of Staub (US Patent 6187540 Issued 2001) and Wohlgemuth (US Patent 6905827 Filed 2002) and in further view of Honda et al (US Patent 6021393 Issued 2000) for the reasons set forth in the Office Action of 6/21/2006 and reiterated below.

The teachings of Beecham, Staub, and Wohlgemuth are presented above in paragraph 5.

The combined references do not teach a method comprising a recording step wherein the identification information and test results information are recorded on the patient's medical information card.

However Honda et al teaches the concept of portable memory cards carried by a patient to store the patient's personal medical information. The card can store the results from medical tests and various personal information. Then when the patient goes to the hospital or to see a doctor for the first time the patient can let the doctor know about his or her morbid state by only presenting the medial information card. (Abstract and Column 3).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Beecham et al so as to have included a recording step wherein the identity information and the test results are recorded on a medical identification card that the patient can keep in order to have achieved the benefits of Honda of providing a medical information card that can store the patients medical data allowing his medical history to be readily available to treating physicians thereby cutting down on hospital mistakes made by doctors.

8 Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Beecham (US Patent 5876926 Issued 1999) in view of Staub (US Patent 6187540 Issued 2001) and Wohlgemuth (US Patent 6905827 Filed 2002) and in further view of Anderson (PG Pub 20010012537).

The teachings of Beecham, Staub, and Wohlgemuth are presented above in paragraph 5.

The combined references do not teach a method further comprising a step of identifying the microarray.

However Anderson et al teach that it is important to have identifiers on the microarrays. Anderson et al teach that the identifiers may be part of the array itself or the array may have a machine readable indicia such as a barcode to provide identification and orientation.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Beecham et al so as to have used a microarray which has a barcode as suggested by Anderson for the benefit of being able to scan the barcode to determine the identity of the microarray.

RESPONSE TO ARGUMENTS

9. In the response filed September 21, 2006, Applicants have described their invention and the benefits of their invention. However the claims have been examined based on what they recite and the claim language is given the broadest reasonable interpretation. The applicant's main argument is that the Wohlgemuth reference does not teach that the different subsets of sequences on the microarray are all analyzed by a hybridization method. This argument has been fully considered but is not persuasive because Wohlgemuth et al teaches that when assessing expression for diagnostics any method known in the art can be used. Specifically Wohlgemuth states that "numerous methods for obtaining expression data are known, and any one or more of these techniques, singly or in combination, are suitable for determining expression profiles in

the context of the present invention. For example, expression patterns can be evaluated by northern analysis, PCR, RT-PCR, Taq Man analysis, FRET detection, monitoring one or more molecular beacon, hybridization to an oligonucleotide array, hybridization to a cDNA array, hybridization to a polynucleotide array, hybridization to a liquid microarray, hybridization to a microelectric array..." (Columns 22-23). Thus Wohlgemuth does in fact teach that the different subsets of sequences on the microarray can be analyzed by one or more different hybridization methods or any other method known in the art. Further, in response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Additionally the applicants argue that probe groups in Wohlegmuth are not used for different purposes. This argument has been fully considered but is not persuasive because Wohlgemuth et al teaches one set of probes on the array can be used to identify markers of a particular disease or condition and that the other set can be used for diagnostic or prognostic purposes. Thus Wohlgemuth does in fact teach that the different subsets of sequences on the microarray are used for different purposes.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda M. Shaw whose telephone number is (571) 272-8668. The examiner can normally be reached on Mon-Fri 7:30 TO 4:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amanda M. Shaw
Examiner
Art Unit 1634

RAM R. SHUKLA, PH.D.
SUPERVISORY PATENT EXAMINER